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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Publication Date 9-26-05  
9-27-05  
Signature *J. Cottle*

**Advisory Committee for Pharmaceutical Science; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Advisory Committee for Pharmaceutical Science.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 25 and 26, 2005, from 8:30 a.m. to 5 p.m.

*Location:* Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person:* Igor Cerny, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: [cerny@cder.fda.gov](mailto:cerny@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/>

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*ohrms/dockets/ac/acmenu.htm* under the heading “Advisory Committee for Pharmaceutical Science (ACPS).” (Click on the year 2005 and scroll down to ACPS meetings.)

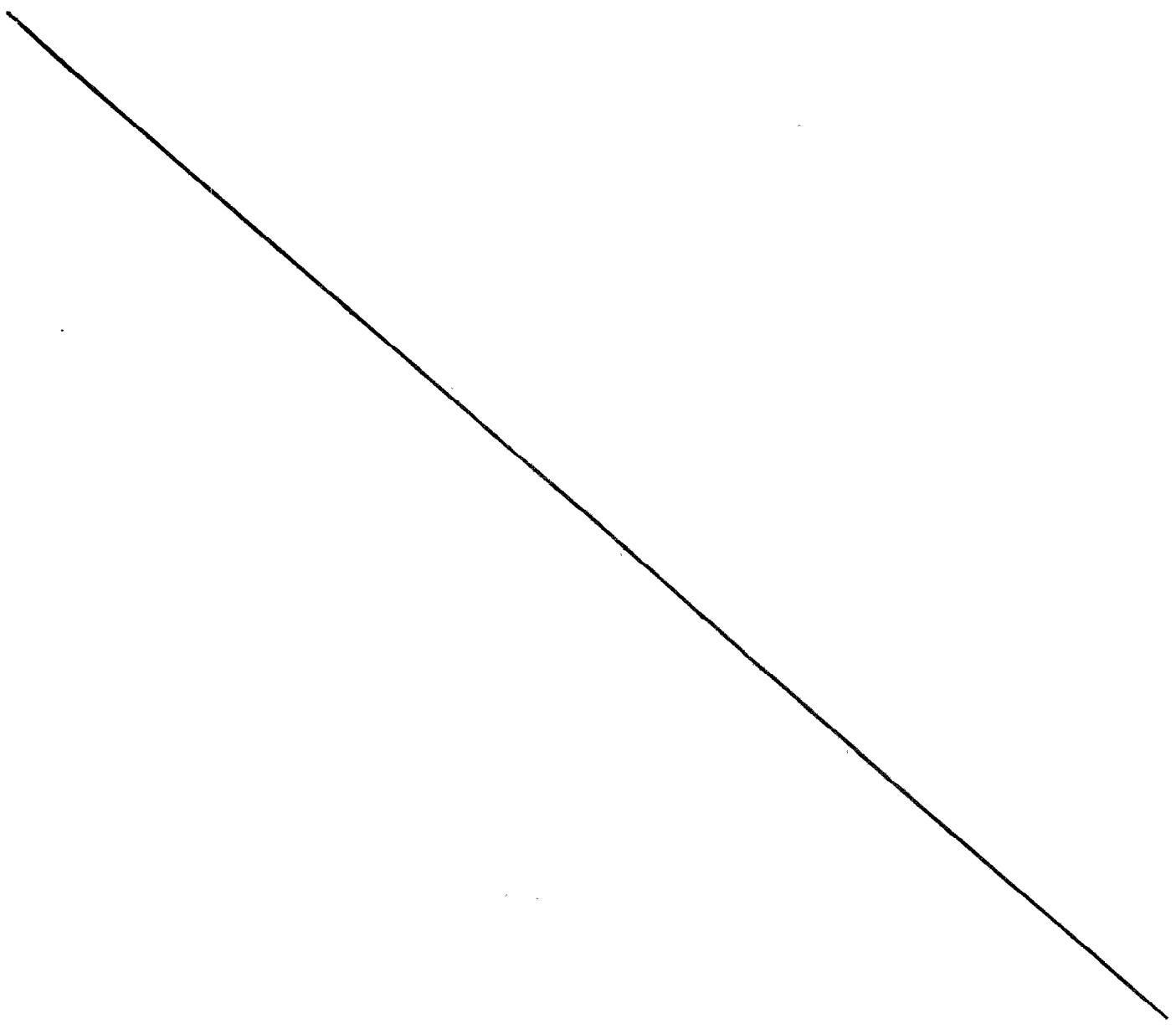
*Agenda:* On October 25, 2005, the committee will do the following: (1) Receive an update on current activities of the Parametric Tolerance Interval Test Workgroup; (2) receive and discuss presentations from the Pharmaceutical Research and Manufacturing Association, the Generic Pharmaceutical Association, and the U.S. Pharmacopeia pertaining to their perspectives on the general topic of Quality-By-Design (QBD) and drug release or dissolution specification setting; and (3) discuss and provide comments on the updated tactical plan under development for the establishment of drug release or dissolution specifications. On October 26, 2005, the committee will do the following: (1) Discuss and provide comments on the general QBD topics of question-based review and alcohol-induced dose dumping and (2) receive and discuss an update on the establishment of a workgroup for the review and assessment of Office of Pharmaceutical Science research programs. Following those items, an awareness topic will be introduced concerning the need to enhance the pharmaceutical education system in the United States.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 17, 2005. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on October 25, 2005, and between approximately 1 p.m. and 2 p.m. on October 26, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 17, 2005, and submit a brief statement of the general

nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

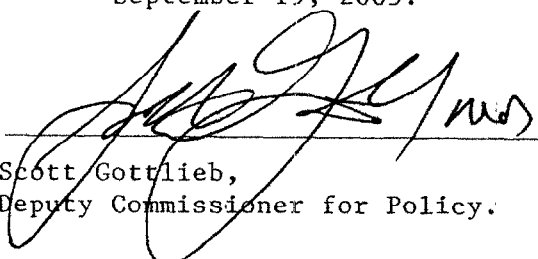
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Igor Cerny at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act  
(5 U.S.C. app. 2).

Dated: 9/19/05  
September 19, 2005.

COPY OF RECORD

  
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Scott Gottlieb,  
Deputy Commissioner for Policy.

[FR Doc. 05-???? Filed ??-??-05; 8:45 am]

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